



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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JFW

In Re Application of: Stephen VESPER

Art Unit: 1645

Appeal No.: 2006-3008

Examiner: Patricia A. Duffy

Application No.: 09/866,793

Filed: May 30, 2001

Washington, D.C.

For: METHODS FOR ISOLATING AND USING FUNGAL...

Atty.'s Docket: VESPER=1

Date: January 16, 2007

Confirmation No. 5682

THE COMMISSIONER OF PATENTS  
U.S. Patent and Trademark Office  
Customer Service Window  
Randolph Building, Appeal Brief-Patents  
401 Dulany Street  
Alexandria, VA 22314

Sir:

Transmitted herewith is a [XX] REPLY BRIEF in the above-identified application.

[ ] Small Entity Status: Applicant(s) claim small entity status. See 37 C.F.R. §1.27.

[XX] No additional fee is required.

[ ] The fee has been calculated as shown below:

|   | (Col. 1)                         |       | (Col. 2)                        |    | (Col. 3)             | SMALL ENTITY         |                | OR | OTHER THAN SMALL ENTITY |                |
|---|----------------------------------|-------|---------------------------------|----|----------------------|----------------------|----------------|----|-------------------------|----------------|
|   | CLAIMS REMAINING AFTER AMENDMENT | MINUS | HIGHEST NO. PREVIOUSLY PAID FOR | ** | PRESENT EXTRA EQUALS | RATE                 | ADDITIONAL FEE |    | RATE                    | ADDITIONAL FEE |
| TOTAL                                     | * 16                             |       | ** 20                           |    | 0                    | x 25                 | \$             |    | x 50                    | \$             |
| INDEP.                                    | * 6                              |       | *** 11                          |    | 0                    | x 100                | \$             |    | x 200                   | \$             |
| FIRST PRESENTATION OF MULTIPLE DEP. CLAIM |                                  |       |                                 |    |                      | + 180                | \$             |    | + 360                   | \$             |
|   |                                  |       |                                 |    |                      | ADDITIONAL FEE TOTAL | \$             | OR | TOTAL                   | \$             |

- \* If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.
- \*\* If the "Highest Number Previously Paid for" IN THIS SPACE is less than 20, write "20" in this space.
- \*\*\* If the "Highest Number Previously Paid for" IN THIS SPACE is less than 3, write "3" in this space.

The "Highest Number Previously Paid For" (total or independent) is the highest number found from the equivalent box in Col. 1 of a prior amendment of the number of claims originally filed.

[XX] Conditional Petition for Extension of Time  
If any extension of time for a response is required, applicant requests that this be considered a petition therefor.

[ ] It is hereby petitioned for an extension of time in accordance with 37 CFR 1.136(a). The appropriate fee required by 37 CFR 1.17 is calculated as shown below:

|                             |                             |
|-----------------------------|-----------------------------|
| Small Entity                | Other Than Small Entity     |
| Response Filed Within       | Response Filed Within       |
| [ ] First - \$ 60.00        | [ ] First - \$ 120.00       |
| [ ] Second - \$ 225.00      | [ ] Second - \$ 450.00      |
| [ ] Third - \$ 510.00       | [ ] Third - \$ 1020.00      |
| [ ] Fourth - \$ 795.00      | [ ] Fourth - \$ 1590.00     |
| Month After Time Period Set | Month After Time Period Set |

[ ] Less fees (\$ \_\_\_\_\_) already paid for \_\_\_ month(s) extension of time on \_\_\_\_\_.

[ ] Please charge my Deposit Account No. 02-4035 in the amount of \$ \_\_\_\_\_.

[ ] Credit Card Payment Form, PTO-2038, is attached, authorizing payment in the amount of \$ \_\_\_\_\_.

[ ] A check in the amount of \$ \_\_\_\_\_ is attached (check no. ).

[XX] The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this application or credit any overpayment to Deposit Account No. 02-4035. This authorization and request is not limited to payment of all fees associated with this communication, including any Extension of Time fee, not covered by check or specific authorization, but is also intended to include all fees for the presentation of extra claims under 37 CFR §1.16 and all patent processing fees under 37 CFR §1.17 throughout the prosecution of the case. This blanket authorization does not include patent issue fees under 37 CFR §1.18.

BROWDY AND NEIMARK, P.L.L.C.

Attorneys for Applicant(s)

Facsimile: (202) 737-3528  
Telephone: (202) 628-5197

By:   
Anne M. Kombau  
Registration No. 25,884



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ATTY.'S DOCKET: VESPER=1

|                            |   |                             |
|----------------------------|---|-----------------------------|
| In re Application of:      | ) | Art Unit: 1645              |
|                            | ) |                             |
| Stephen J. VESPER          | ) | Examiner: Patricia A. DUFFY |
|                            | ) |                             |
| Appeal No.: 2006-3008      | ) | Confirmation No. 5682       |
|                            | ) |                             |
| Appln. No.: 09/866,793     | ) |                             |
|                            | ) |                             |
| Filed: May 30, 2001        | ) | Washington D.C.             |
|                            | ) |                             |
| For: METHODS FOR ISOLATING | ) | January 16, 2007            |
| AND USING FUNGAL...        | ) |                             |

REPLY BRIEF

Honorable Commissioner for Patents  
U.S. Patent and Trademark Office  
Customer Service Window, Mail Stop Appeal Brief-Patents  
Randolph Building  
401 Dulany Street  
Alexandria, VA 22314

Sir:

Replying to the Examiner's Answer mailed November 17, 2006, please enter the following Reply Brief:

I. Claims 23 and 25-29 are not Unpatentable under 35 U.S.C. 103(a) over Sakaguchi et al. in view of Harlow

It is respectfully submitted that the entire application is based upon the premise that hemolysin producing fungi produce hemolysins that are specific to each fungus. It is clear from paragraph 0024 of the specification as filed that the hemolysins produced by the fungi are specific to each

fungus. Otherwise, an assay for an individual fungus would be impossible. Paragraph 0034 states:

Exposure to low levels of hemolysin can lead to potassium ion depletion in monocytes, which can lead to activation of interleukin-converting enzyme. This in turn can lead to rapid and massive release of mature IL-beta. In addition, T-lymphocytes that leak potassium ions undergo programmed cell death (apoptosis). For this reason, it is critical to identify the source of the hemolysin in a human or other animal which may have been exposed to a hemolysin-producing fungus and immediately begin treatment. [emphasis added]

It is clear from the above that hemolysins specific to each fungus are needed in order to identify the source of the hemolysin. That is, one must identify the fungus that produced the hemolysin so that treatment can begin.

It is respectfully submitted that the Examiner has misquote paragraph 0024 of the specification as filed. This paragraph reads, "By growing strains of hemolysin producing fungi *in vitro* and isolating the hemolysin it is now possible to use the protein obtained to identify fungi which are isolated from buildings, homes, schools and the like."  
[emphasis added]

There is nothing in Sakaguchi that even suggests that individual hemolysins can be used to identify individual fungi. Sakaguchi knew that the rat had been exposed to the fungus, and was trying to determine how the infection

progressed through the rat's tissues. The methods claimed herein, however, are for determining if an animal has been exposed to a specific hemolysin-producing fungus. Since Sakaguchi already knew that the rat had been exposed to the fungus, the Sakaguchi method has nothing to do with the presently claimed method.

**II. Claim 33 is not anticipated by Sakaguchi et al.**

Claim 33 is directed to a method for determining if an animal has been exposed to a specific hemolysin-producing fungus. Sakaguchi already knew that the animal had been exposed to the fungus, as Sakaguchi had administered the fungus to the animal.

Contrary to the Examiner's assertion that the intention or purpose of the invention as set forth in the preamble is not seen as limiting, it is respectfully submitted that the preamble in this case give life to the claimed invention. To read claim 33 as covering all assays detecting fungal hemolysin in a sample would be divorced from reality. As in *Corning Glass Works v. Sumitomo Electric*, 868 F.2d 1251; 9 USPQ 2d 1962 (Fed. Cir. 1989). The specification makes it clear that the inventors were working on the particular problem of identifying hemolysin-producing fungi and identifying if an animal had been exposed to one of such

fungi. As in *Corning, supra*, the preamble gives life and meaning to the claim and provides further positive limitations to the invention so claimed (9 USPQ 2d 1966).

III. Claims 23-29 and 33 Comply with the Written Description Requirement

It is respectfully submitted that the claimed invention is supported by the written description, as there would be no point to the claimed method if the hemolysin produced by the fungus was not unique to that fungus. It is immaterial that the method differential among strains or species of fungus. What is claimed is that the method determine if an animal has been exposed to a specific hemolysin-producing fungus [emphasis added]. This can only be accomplished if each hemolysin-producing fungus has a hemolysin that is specific for that fungus, so that the fungi can be differentiated from each other. As stated in paragraph 0034, the test is to enable one to identify the source of the hemolysin in a human or other animal that has been exposed to such a fungus. Unless the hemolysin is specific for each hemolysin-producing fungus, this assay would be worthless other than for a determination that the infection was from a hemolysin-producing fungus.

One skilled in the art reading the present specification and claims would certainly understand that the fungi produce hemolysins that are specific to each fungus producing the hemolysin. It is this specificity that makes it possible to identify a particular fungus that infects a human or other animal. It is respectfully submitted that one skilled in the art would appreciate the requirement for this specificity for the assay to be useful.

**IV. Claims 30-32 Comply with the Written Description**

**Requirement**

It is clear that paragraphs 0036 and 0037 of the specification as filed teach determining if a building holds fungi that produce hemolysin. The building can be assayed for problematic fungi by taking a sample from the building and assaying it for specific hemolysin-producing fungi. The specification *in toto* explains how one assays for hemolysin-producing fungi. It is respectfully submitted that one skilled in the art could readily appreciate that a building sample can be assayed in the same manner as a sample from an animal.

V. Claims 30-32 Comply with the Enablement Requirement

One skilled in the art, reading the present specification, would readily appreciate that a specific fungus can be detected using antibodies that bind to the fungal hemolysin or active fragments thereof. One skilled in the art of immunoassay is certainly capable of extrapolating methods for detecting samples whether obtained from buildings or animals. It is well known that a specification need not provide the exact wording used in the claims if one skilled in the art can understand what is meant in the disclosure in relation to the claims.

VI. Claims 23-26 Comply with the Written Description Requirement

It is respectfully submitted that one skilled in the art, reading the present specification, would conclude that the fungi being assayed have hemolysins specific to that particular fungus. If the hemolysins were not specific to individual fungi, there would be no point to the present determination, as the only thing determined would be the presence of any hemolysin-producing fungus. It is clear to one skilled in the art that the hemolysin must be specific to a particular fungus for the assay to be useful.

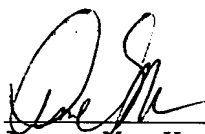
VII. Claims 30-32 Particularly Point Out and Distinctly  
Claim the Subject Matter Which Applicant Regards as the  
Invention

The method of claims 30-32 is for determination if a building contains a hemolysin-producing fungus. One obtains a sample. Then, if hemolysin-producing fungi are present in the building, there is hemolysin in the sample and hemolysin can be obtained from the sample. The remaining steps of the claims infer that there is hemolysin in the sample. It is respectfully submitted that one skilled in the art can readily understand the method claimed herein.

The rejections should be reversed and such is respectfully prayed.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.  
Attorneys for Applicant

By:   
\_\_\_\_\_  
Anne M. Kornbau  
Registration No. 25,884

AMK:srd  
Telephone No.: (202) 628-5197  
Facsimile No.: (202) 737-3528  
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